Six Sigma Process - Improvement of Regional STAT Medical Laboratory Service

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Introduction

Six Sigma at Quest Diagnostics

The Six Sigma method was introduced in the 1980s when Motorola pioneered changes to:

- measure defects per million opportunities (DPMO) to provide a better understanding of defect rates and process performance
- establish a new business culture that uses process-driven methodology

Literally, Six Sigma stands for 3.4 DPMO—virtual perfection. The Six Sigma business philosophy thus focuses on reducing overall defects and performance variation as defined by the "Voice of the Customer" (VOC). The Quest Diagnostics Six Sigma program incorporates both Six Sigma and Lean principles and process tools to improve performance. Since 2000, more than 160 business leaders throughout Quest Diagnostics have become Black Belts (full-time Six Sigma project leaders). These Black Belts work with every Quest Diagnostics business unit and functional area across the company.

This report describes the implementation of Six Sigma methods to reduce the occurrence of "STAT test turn around times exceeding 2 to 3 hours" at the St Louis business unit.

Business Case/Problem Statement

STAT test turn-around times at our regional laboratory were not meeting customer requirements of 2 to 3 hours—4.5% of STAT orders were delayed.

Some of the reasons for delays in STAT handling were known:

- STAT processes consist of complicated manual piecework and operator workflow.
- Off-line manual STAT process cannot be easily monitored.
- There is no one measure that can monitor STAT performance from "call for STAT" to "results release."
- STAT performance also declined after the logistics department implemented staffing "improvements."

The primary purpose of this Six Sigma project was to identify and remedy the underlying causes of the defects in STAT cycle time at the St Louis business unit. This project required close collaboration with all aspects of the laboratory operation.

Method

Below is an overview of the Six Sigma procedures used in this project:

Define	Establish the business case, the customer expectations (VOC); what is Critical To Quality (CTQ) to the customer; definition of primary metrics (Ys); defect definitions; identify the Suppliers, supplier Inputs, high level process, process Output, Customers (SIPOC); roles and responsibilities of team members
Measure	Study and map the process steps; establish data collection plan; assess capabilities of measurement systems; measure baseline performance of the process (Ys and defects); establish goals for defect reduction; preliminary stratification of problems
Analyze	Identify the variables (Xs) that influence process performance (Process Maps, FMEA, YX matrix, stratification graphs, etc); establish and test hypothesized effects of variables (Xs) upon process (Ys); identify improvements
Innovative Improvement	Perform cost-benefit analysis of improvements; pilot improvements; control chart measure the improvement performance
Control	Establish a control plan for the process owner; document and standardize the improvements; continue to control chart monitor the improved process

Method (cont)

Define

The project foundation is established during the "define" stage. The team members are chosen, a high level understanding of project processes is established, and detailed plans for data collection are made. The project charter sets forth the expectations of the project. Along with the business case and problem statement (outlined above), the charter establishes the project scope and the project goal.

Scope

Start: Call for STAT pickup

Stop: Release of STAT results

Exclude: Routine testing included on STAT orders

Goal

Reduce Logistics and Processing defects by 50%

- Current Process Capability
  - Logistics: 63,966 DPMO
  - Processing: 66,503 DPMO

A SIPOC chart for STAT testing, created as part of the define stage, is aligned with the overall scope of the project.

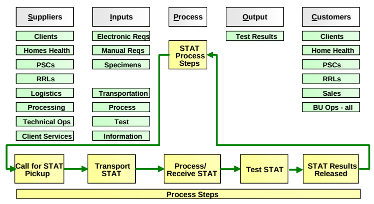

Figure 1. SIPOC chart aligned with overall scope of STAT testing project.

Measure

The Six Sigma process requires that the team map all steps and decisions and establish key measures of performance for the process as defined by the SIPOC chart. Figure 2 depicts one of the process maps developed for this project.

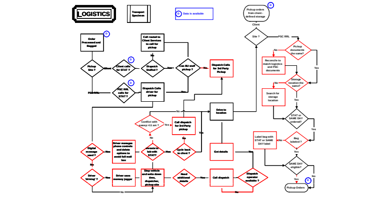

Figure 2. Logistics process map, one of the many process maps created to document the details of workflow. Decisions and workflow steps denoted in red represent points with a potential for defect (increased cycle time).

Method (cont)

Measurement of process capability is key to understanding under what circumstances failure will occur. With the existing specimen processing system, STAT orders are handled on a first in, first out basis. Only 1 of the 4 specimen processing workstations can process STAT requests. Based upon performance observations, a regression calculation predicted that specimen processing performance would fail cycle time expectations when more than 14 STATs arrived within a 30-minute interval (data not shown).

Analyze

To better understand the overall STAT process, we incorporated measurement data into solution-oriented tools. Cause and effects (Ishakawa) diagrams are used to link potential process map defects to the 6 major categories of defects that could lead to process failure. The major categories of defects include personnel, methods, measurements, machines, and environmental effects (Fig 3).

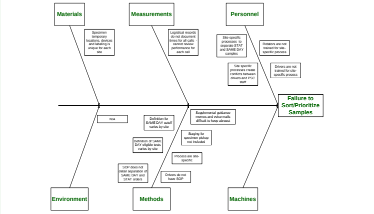

Figure 3. Representative cause and effects (Ishakawa) diagram for patient service centers (PSCs) and drivers.

Failure Modes and Effects Analysis (FMEA) is a powerful quality tool that calculates a ranking of process failures as a function of the severity of defect effects, the ability to detect defects, and current controls to prevent defects. The FMEA tool also documents improvements, when and who made improvements are implemented. Post-improvement process failure effects, detection, and controls are recalculated to demonstrate improved process performance (Fig 4).

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Resp.	Actions Taken
What is the Process Step/ Input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent either the Cause or the Failure Mode? Should include an SOP number.	How well can you detect cause or FM?		What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes.	Who is Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year.
Dispatch receipt of PSC STAT call	STAT not picked up in timely manner	STAT delayed	7	PSC missed or lost track of STAT	10	None	9	630	Develop process, SOP and implement MegaSys for logging and tracking STATs	Logistics team	Pilot the first 2 weeks in July; review week 3 and 4 in July; train all Logistics staff for August 31 implementation
Dispatch receipt of PSC STAT call	STAT not picked up in timely manner	STAT delayed	7	Dispatch missed documenting or lost track of STAT tracking; dispatch operators (at up to 3 stations) must share a common handwritten log book- STAT entries can be missed	10	Manual log to record STAT calls	9	630	Develop process, SOP and implement MegaSys for logging and tracking STATs	Logistics team	Pilot the first 2 weeks in July; review week 3 and 4 in July; train all Logistics staff for August 31 implementation
Dispatch receipt of PSC STAT call	STAT not picked up in timely manner	STAT delayed	7	Driver missed call or lost track of STAT tracking	10	Manual log to record STAT calls	9	630	Develop process, SOP and implement MegaSys for logging and tracking STATs	Logistics team McClure	Pilot the first 2 weeks in July; review week 3 and 4 in July; train all Logistics staff for August 31 implementation
Delivery of STAT	Unable to Pickup STAT	STAT delayed	7	STAT in process or traffic delay	9	use third party backup	9	567	Continue to use third party service	N/A	

OCCURRENCE RATING (example)

	Rating	Time Period	Probability
BAD	10	More than once per day	> 30%
	9	Once every 3-4 days	<= 30%
	8	Once per week	<= 5%
	7	Once per month	<= 1%
	6	Once every 3 months	<= 0.03%
	5	Once every 6 months	1 per 10,000
	4	Once per year	6 per 100,000
	3	Once every 1-3 years	6 per million
	2	Once every 3-6 years	3 per 10 million
GOOD	1	Once every 6-100 years	2 per billion

DETECTION RATING (example)

	Rating	Definition
BAD	10	Defect caused by failure is not detectable
	9	Occasional units are checked for defects
	8	Units are systematically sampled and inspected
	7	All units are manually inspected
	6	Manual inspection with mistake-proofing modifications
	5	Process is monitored (SPC) and manually inspected
	4	SPC used with an immediate reaction to out of control conditions
	3	SPC as above with 100% inspection surrounding out of control conditions
	2	All are automatically inspected
GOOD	1	Defect is obvious and can be kept from affecting customer

Figure 4. FMEA chart. This truncated chart is for purposes of illustration only. The full chart contains many more rows and also has columns to track severity, occurrence, detectability, and risk priority number (RPN) after corrective actions are taken.

Method (cont)

Innovative Improvement

Key areas of improvement identified by the project include:

- Need for standardized procedures
- Need for visual controls to assist specimen sorting
- Need to establish key measures for monitoring defects
- Need to update manual transcription processes to on-line electronic tools
- Need to modify specimen processing staffing patterns

We therefore implemented a standard operating procedure (SOP) for STAT handling at patient service centers (PSCs) and rapid response laboratories (RRLs). Standard specimen drop-off forms were also implemented, so that nurses now see the same form at each PSC and RRL, as well as at the main laboratory. Figure 5 illustrates some of the other improvements put into effect.

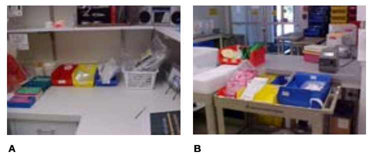

Figure 5. Innovative improvements. A) The improved procedures incorporate visual, color-coded controls into the STAT handling process: red bins are used for STAT requests at all sites. B) The visual color-coded controls into all operations at the regional testing facility—shown is an example of the receiving area in the specimen processing department.

Changes were also implemented in specimen processing. Previously, only 1 specimen processing workstation could process STAT requests. With the improved system, additional work stations are "recruited" as the number of STAT requests in the queue increases, in increments of 4 STATs, until all 4 work stations at the laboratory are processing STAT requests. Regression analysis with the new system in place predicts that processing station failure now does not occur until more than 48 STAT orders arrive within a 30-minute period; and more than 48 STATs per half-hour interval has not been observed (Fig 6).

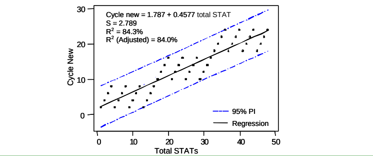

Figure 6. Regression analysis with new STAT processing hierarchy in place, predicting that processing station failure now will not occur until more than 48 STAT orders arrive within a 30-minute period (vs 14 STAT orders prior to improvements). Fitted line plot: cycle new vs total STATs.

Results

Control

The Six Sigma process uses control charts to monitor how the process is performing (Fig 7). Overall, STAT logistical performance improved by 53% (DPMO of 63,966 improved to 29,492).

Results

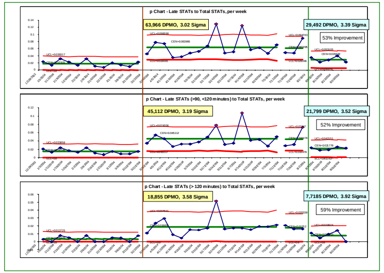

Figure 7. Proportions control chart (p-chart) for logistics. Proportion of late results for A) all STAT requests; B) STATs delivered in 90–120 min; C) STATs delivered in >120 minutes. Left: historical data. Middle: increased numbers (and variance) of defects are observed after the logistics department implemented staffing "improvements" in March 2004. The break toward the right of the middle section indicates initiation of pilot solutions at limited sites. Right: STAT performance improved after innovative improvements were fully deployed.

The control plan is an integral part of maintaining the gains in the Six Sigma process (Fig 8). When a variance is observed (control chart trend or out-of-control measure), the control plan describes what steps to take and who is responsible.

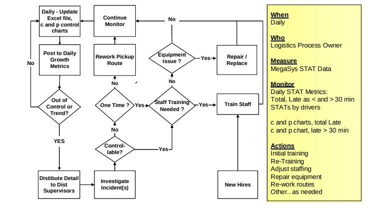

Figure 8. Logistics control plan. Another control plan, not shown, was created for technical operations.

Conclusions

The Six Sigma methods employed in this project allowed us to

- Identify the sources of errors leading to the defects in STAT handling
- Implement effective interventions to correct the errors
- Monitor the success of these interventions and quickly recognize recurrence of the problem